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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,371	03/22/2001	Graham McCreath	8117-14	4297

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EXAMINER

WEBER, JON P

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 12/04/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/814,371	MCCREATH ET AL.	
	Examiner	Art Unit	
	Jon P Weber, Ph.D.	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23,26,27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 16-23,26,27 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____ |

Status of the Claims

Claims 1-23, 26-27 and 29 have been presented for examination.

Election/Restrictions

Applicant's election of Group I, claims 1-15 in Paper No. 12, filed 04 November 2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 16-23, 26-27 and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions group, there being no allowable generic or linking claim. Election was made effectively **without** traverse in Paper No. 12. It is suggested that the non-elected claims be canceled in response to this Office action to expedite prosecution.

Claim Objections

Claim 7 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 5 (identical). When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1651

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, there are no clear method steps. However, the process disclosed in the specification involves the following minimal steps:

- a) Precipitating fibrinogen from milk in the presence of one or more of lysine, lysine analog, or ϵ -aminocaproic acid, and
- b) Separating the precipitated fibrinogen from the whey that contains protease enzymes present in the milk.

Similarly, claim 3 is incomplete having only step (a).

Claims 1 and 6 recite "transfer of protease enzyme ... into the whey phase". Transfer is not occurring. What happens is that the proteases are separated into what will become the whey phase after precipitating the fibrinogen.

Claim 15 is so confusing that it is not understood.

Dependent claims are rejected as being dependent from a rejected base claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garner et al. (US 5,639,940) in view of Tripodi (WO 9213495) and further in view of Vukovich et al. (1980) and Lord (US 6,037,457).

Garner et al. (US 5,639,940) discloses the transgenic production of fibrinogen (human or non-human, column 4, line 30-33) in milk of various livestock (column 2, lines 9-15; column 4, lines 15-29). The fibrinogen is collected and recovered from the milk using standard practices such as precipitation, filtration and protein chromatography (column 2, line 65; column 9, lines 23-25). Garner et al. (US 5,639,940) lacks precipitating fibrinogen from milk in the presence of one or more of lysine, lysine analog, or ϵ -aminocaproic acid, or the specific HIC chromatography.

Tripodi (WO 9213495) disclose precipitating fibrinogen from plasma with PEG in buffer containing ϵ -aminocaproic acid. The buffer system is said to be important because it prevents premature conversion of fibrinogen into fibrin (page 8, line 34 to page 9, line 21).

Vukovich et al. (1980) teach that fibrinogen can be highly purified using HIC with for example, butyl-sepharose.

Lord (US 6,037,457) teach that recombinantly produced fibrinogen can be purified by various techniques known in the art including: precipitation and HIC (column 6, lines 36-52).

A person of ordinary skill in the art at the time the invention was made would have been motivated to purify fibrinogen transgenically produced in milk according to Garner et al. (US 5,639,940) by precipitation from the milk in the presence of one or more of lysine, lysine analog, or ϵ -aminocaproic acid as taught by Tripodi (WO 9213495), and further HIC chromatography as taught by Vukovich et al. (1980) and Lord (US 6,037,457) because Garner et al. (US 5,639,940)

Art Unit: 1651

states that precipitation and chromatography may be used to purify the fibrinogen and Tripodi (WO 9213495) teach that precipitation with ϵ -aminocaproic acid is necessary to prevent premature conversion of fibrinogen to fibrin by plasmin, and because both Vukovich et al. (1980) and Lord (US 6,037,457) disclose that fibrinogen can be highly purified by HIC as the chromatography.

It is clear that the state of the art recognizes that plasmin is a component of milk and poses a potential problem of premature conversion of fibrinogen into fibrin for transgenically produced fibrinogen in milk (admitted at page 3 of the disclosure; see also Kutzko et al., WO 9742385 cited in IDS). This is the same problem, albeit not as severe, as that solved by Tripodi (WO 9213495). Precipitation of the fibrinogen from the fluid in the presence of ϵ -aminocaproic acid (a plasmin inhibitor) prevents premature conversion and separates the fibrinogen from the plasmin which remains in solution.

The subsequent purification of fibrinogen by known conventional chromatography methods is suggested by Garner et al. (US 5,639,940). Vukovich et al. (1980) and Lord (US 6,037,457) explicitly suggest using HIC.

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to precipitation transgenically produced fibrinogen from fluid such as milk in the presence of ϵ -aminocaproic acid and to further purify the fibrinogen by HIC.

No claims are allowed.

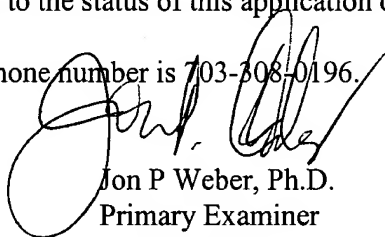
Application/Control Number: 09/814,371
Art Unit: 1651

Page 6

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
December 2, 2002